



UNITED STATES PATENT AND TRADEMARK OFFICE

1

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,523	11/21/2003	Kenneth J. Rothschild	AMBER-08501	3365

7590 05/23/2006

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, CA 94105

EXAMINER

SCHLAPKOHL, WALTER

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,523

Applicant(s)

ROTHSCHILD ET AL.

Examiner

Walter Schlapkohl

Art Unit

1636

Waf

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/2/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 16-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 3/2/2006.
Claims 1-37 are pending. Claims 16-37 are withdrawn.

Election/Restrictions

Claims 16-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/2/2006.

Applicant traversed the restriction (election) not only on the grounds that the group assignments were improper, but also on the grounds that the restriction did not include Applicant's independent claims. Applicant further traversed the restriction requirement on the grounds that Examiner's reasons for an "undue burden" were unsupported and did not meet statutory standards because, Applicant argues, the MPEP requires "that an undue burden requires Groups having separate classifications" (see page 2, Section IA of the Remarks filed 3/2/2006). Applicant further argues that Examiner has not shown that "elements" have separate status in the art or involve a different field of search (ibid). Applicant further argues that more than one

Art Unit: 1636

sequence is not an undue search burden. Applicant further argues that Groups restricted to SEQ ID NOS: 5-9 and the APC/NF1/NF2/BRCA1/BRCA2 genes comport with standard MPEP guidelines with respect to Markush claims and that Examiner is "improperly attempting to redefine scientific dogma by arguing that nucleic acids of different sequences belong to a different physical and/or chemical class." Applicant further argues that the five members of Claim 7 (and other identical claims) and the five members of Claim 8 meet the intent of "sufficiently few in number" such that the Examiner is not faced with any undue burden and that, further, the Markush elements meet the "closely related" requirement because they are all either nucleic acids or cancer causing genes (see page 3, section IB of the Remarks submitted 3/2/2006). Applicant further argues that increased database size is not an undue burden and that Examiner has improperly asserted new USPTO policy.

Applicant's arguments have been carefully considered and have been found persuasive in part. Applicant's argument that the restriction did not include Applicant's independent claims is incorrect. The independent claims referred to by Applicant were included in the restriction requirement as linking claims. Indeed, independent claims 1 and 9 have been examined in the instant Office Action as part of the elected Group. Applicant's

Art Unit: 1636

argument regarding lack of search burden with regard to the template genes is not persuasive because the claimed genes are structurally and functionally different and distinct, i.e., they consist of nucleotide sequences which are chemically and functionally different. Genes include promoters, 5' and 3' untranslated regions, exons and introns; not only are each of the claimed genes chemically and structurally different, but also the subregions of the claimed genes are chemically and structurally different. Thus, a search for each of the Groups of the restriction would, indeed, require a different field of search and pose a serious search burden. Applicant's argument that an undue burden requires Groups having separate classifications is also found unpersuasive because, as Applicant later notes

...a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search...

(MPEP §803 ¶5) (emphasis added). However, Applicant's arguments regarding search burden to the extent that they pertain to the SEQ ID NOs listed in claims 7 and 14 were found persuasive. To that end, Examiner has agreed to rejoin Groups I, VI, XI, XVI, and XXI, drawn to a reaction mixture and a kit comprising two oligonucleotide primers and a template, wherein the primers

Art Unit: 1636

comprising a sequence encoding for an epitope marker and a region of complementarity to a region of the APC gene, thus rendering Applicant's other arguments moot.

The restriction is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to because Figure 15 and Figure 17 are not labeled with a figure number. Furthermore, none of the corrected drawings submitted on 9/9/2004 have been labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be

necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because a sequence list in both paper and computer readable forms was submitted after the filing date of the application but the sequence list was not accompanied by the a statement that the paper copy and computer readable do not include new matter. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through

Art Unit: 1636

1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Specification

The disclosure is objected to because of the following informalities: the first line of the specification should be amended to include the updated status of application 09/813,197 which is no longer copending and which has become patent number 6,875,592.

Appropriate correction is required.

Claim Objections

Claims 8 and 15 are objected to because of the following informalities: claims 8 and 15 are drawn to non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 9 & 14, and therefore dependent claims 2-6, 8, 10-13 & 15, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 9 & 14 recite the term "epitope marker." Claims 1, 7, 9 & 14 are vague and indefinite in that it is unclear what the metes and bounds of the term "epitope marker" are. The term is not defined in the specification. Does Applicant intend any peptide sequence which can be recognized by an antibody or does Applicant intend a more narrow set of embodiments such as the commonly-found affinity binding tags corresponding to SEQ ID NOs: 5-9?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 1636

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to reaction mixtures and kits comprising a first primer comprising i) a sequence corresponding to a promoter, ii) a sequence corresponding to a ribosome binding site, iii) a start codon, and iv) a sequence coding for a first epitope marker; and b) a second primer comprising i) at least one stop codon, and ii) a sequence encoding for a second epitope marker. Some claims are further limited to such reaction mixtures/kits that further comprise a template and to such reaction mixtures/kits wherein the primers further comprise regions of complementarity to the template (any region of the APC gene) and wherein the regions of complementarity are greater than 15 bases in length. Some claims are also further limited to such reaction mixtures/kits wherein the second epitope marker is selected from the group consisting of SEQ ID NOs: 5, 6, 7, 8 and 9. The claims encompass any reaction mixture/kit comprising any first primer with a sequence, however long or short and of whatever composition as long as it corresponds to any portion of a promoter; with a sequence, however long or short and of whatever composition as long as it comprises any portion of any sequence corresponding to a ribosome binding site; as well as

Art Unit: 1636

any sequence, however long or short and of whatever composition, coding for a first epitope marker. The claims further encompass any reaction mixtures/kits wherein the second primer comprises at least one stop codon and further comprises any sequence encoding for any second epitope marker. The claims do not provide any structural information with regard to the sequences corresponding to a promoter, sequences corresponding to a ribosome binding site, or sequences encoding for a first epitope or second epitope marker. Thus, the rejected claims comprise a set of nucleic acid sequences that are defined by their function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes a prokaryotic mRNA ribosome binding site "which usually contains part or all of a polypurine domain UAAGGAGU known as the Shine-Dalgarno (SD) sequence" (see page 15, first paragraph). The specification also describes a reverse primer comprising a region encoding a C-terminus marker such as a HIS-

Art Unit: 1636

tag (see, e.g., page 15, first full paragraph). The specification also refers to other "epitope sequences" such as the C-myc, Flag, HA and StrepTag tags as well as to "markers" such as "native amino acids coupled with a detectable label" (see, e.g., page 30, lines 7-8). However, the specification does not describe a single "epitope marker." As examples of such primer sequences which meet the claim limitations, the specification discloses two examples of a first primer comprising i) a sequence corresponding to a promoter, ii) a sequence corresponding to a ribosome binding site, iii) a start codon, and iv) a sequence coding for a first epitope marker (see SEQ ID NOs: 11 and 13 on pages 113 and 115, respectively), although the sequence corresponding to a ribosome binding site is not indicated in SEQ ID NO: 13. The specification also discloses two examples of a second primer comprising i) at least one stop codon, and ii) a sequence encoding for a second epitope marker. However, no description is provided of a single set of first and second primers wherein the primers further comprise a region of complementarity of greater than 15 nucleotides in length to any region of the APC gene.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only

Art Unit: 1636

representative of two sets of primers, and those do not even meet all of the claim limitations, which require a region of complementarity to a region of the APC gene greater than 15 bases in length. The results are not necessarily predictive of any other sequences capable of binding to a ribosome or coding for a first or second epitope marker. Thus it is impossible to extrapolate from the examples described herein those nucleic acid molecules that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of kits/reaction mixtures comprising primers which meet all the claim limitations or such kits/reaction mixtures comprising primers that further comprise any sequence corresponding to a promoter, any sequence corresponding to a ribosome binding site or any sequence encoding a first and/or second epitope marker. Rowan et al (*Human Mutation* 9:172-176, 1997) teach a reaction mixture comprising i) a sequence corresponding to a promoter, ii) a sequence corresponding to a ribosome binding site, iii) a start codon, and iv) a sequence coding for a first epitope marker; and b) a second primer comprising i) at least one stop codon, and ii) a sequence encoding for a second epitope marker (see entire document, especially Figure 1 and page 173, 2nd

Art Unit: 1636

column); however Rowan et al do not teach such a reaction mixture/kit wherein the second epitope marker is selected from the group consisting of SEQ ID NOs: 5, 6, 7, 8 and 9.

Given the very large genus of nucleic acid molecules encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to the primer sequences capable of fulfilling the claim limitations of claims 1-15, the skilled artisan would not have been able to describe the broadly claimed genus of first primer sequences that bind a ribosome or, at a minimum, correspond to a ribosome binding site, and further comprise a sequence corresponding to a promoter, and further comprise a sequence which encodes a first epitope marker. Neither would the skilled artisan have been able to describe the broadly claimed genus of second primer sequences comprising i) at least one stop codone and ii) a sequence encoding for a second epitope marker. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those nucleic acid sequences that necessarily satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1-15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8, 9-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowan et al (*Human Mutation* 9:172-176, 1997).

Note: for purposes of this rejection only, "epitope marker" has been interpreted to encompass any sequence encoding a peptide capable of being recognized by an antibody and the term "kit" has been interpreted to include any teaching or reference wherein the components of the kit are utilized within the same method or wherein the kit components have been purposely grouped together.

Rowan et al teach a PCR reaction mixture comprising a) a first oligonucleotide primer comprising i) a sequence corresponding to a promoter, ii) a sequence corresponding to a ribosome binding site, iii) a start codon, and iv) a sequence coding for a first epitope marker; and b) a second oligonucleotide primer comprising at least one stop codon (see

Art Unit: 1636

nucleotides 6-8 of "APC 15J rev" primer, page 173, 2nd column (not in frame)), as well as a sequence encoding for a second epitope marker, i.e., that portion of the APC gene for which it codes (see entire document, especially Figure 1 and page 173, 2nd column, section titled "Oligonucleotide Sequences"). Rowan et al also teach this PCR reaction mixture, wherein the reaction mixture further comprises template (ibid). Rowan et al also teach that both the first and second primers comprise a region of complementarity to the template wherein said region of complementarity is greater than 15 bases in length. Regarding claims 8 and 15, Rowan et al teach such a reaction mixture/kit wherein the template comprises a region of the APC gene.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowan et al (*Human Mutation* 9:172-176, 1997) in view of Suzuki et al (*Genes, Chromosomes & Cancer* 21:290-297, 1998).

Note: for purposes of this rejection only, "epitope marker" has been interpreted to encompass any sequence encoding a peptide capable of being recognized by an antibody and the term "kit" has been interpreted to include any teaching or reference wherein the components of the kit are utilized within the same method or purposely grouped together.

Rowan et al teach a PCR reaction mixture comprising a) a first oligonucleotide primer comprising i) a sequence

Art Unit: 1636

corresponding to a promoter, ii) a sequence corresponding to a ribosome binding site, iii) a start codon, and iv) a sequence coding for a first epitope marker; and b) a second oligonucleotide primer comprising at least one stop codon (see nucleotides 6-8 of "APC 15J rev" primer, page 173, 2nd column (not in frame)), as well as a sequence encoding for a second epitope marker, i.e., that portion of the APC gene for which it codes (see entire document, especially Figure 1 and page 173, 2nd column, section titled "Oligonucleotide Sequences"). Rowan et al also teach this PCR reaction mixture, wherein the reaction mixture further comprises template (ibid). Rowan et al also teach that both the first and second primers comprise a region of complementarity to the template wherein said region of complementarity is greater than 15 bases in length. Regarding claims 8 and 15, Rowan et al teach such a reaction mixture/kit wherein the template comprises a region of the APC gene. Importantly, Rowan et al teach this primer/template reaction mixture in the context of a protein truncation test for identifying frameshift and nonsense mutations within the APC gene. Part of the novelty of the teaching of Rowan et al is the incorporation of a myc tag (SEQ ID NO: 6) into the first primer to allow "for all normal and truncated proteins to be identified," to avoid the use of radioisotope, and to allow for

integration into all protein truncation tests, regardless of the gene being examined (see page 172, Abstract and page 175, paragraph bridging first and second columns).

Rowan et al do not teach such a reaction mixture wherein the second oligonucleotide primer comprises a sequence encoding an epitope marker selected from the group consisting of SEQ ID NOS: 5, 6, 7, 8 and 9.

Suzuki et al teach a variation on the protein truncation test for identifying frameshift and nonsense mutations comprising PCR reactions mixtures comprising a first and second primer. In the yeast-based protein truncation test (YPTT) of Suzuki et al, the region of complementarity is adjacent to an PGK terminator peptide sequence (comprising a stop codon), which allows Suzuki et al "to detect truncating mutations adjacent to the downstream primer" (see page 293, second column, first paragraph). Suzuki et al further teach a second variation of the YPTT in which "a truncating mutation can be detected simply by testing whether the yeast transformants express a carboxy-terminal marker peptide or not" (see page 295, paragraph bridging the first and second columns). The marker would be fused in-frame to the end of the tested DNA fragment (ibid).

It would have been obvious to one of ordinary skill in the art to combine the references of Rowan et al and Suzuki et al

Art Unit: 1636

because both references teach improved methods for performing a protein truncation test. Furthermore, it would have been obvious to use the c-myc tag of SEQ ID NO: 6 since Rowan et al teach it's successful incorporation into the upstream primer.

One of ordinary skill in the art at the time the claimed invention was made would have been motivated to utilize a second, carboxyl terminal epitope marker as taught by Suzuki et al because Suzuki et al teach its use would allow for the detection of truncation mutations adjacent to the downstream primer.

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when incorporating a second epitope marker of SEQ ID NO: 6 in the second primer of the reaction mixture as taught by Rowan et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the

Art Unit: 1636

examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-13 and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 20 and 44-49 of copending Application No. 10/339,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8-13 and 15 are drawn to a reaction mixture comprising a first primer comprising a sequence corresponding to a promoter, a sequence corresponding to a ribosome binding site, a start codon, and a sequence coding for an epitope marker as well as a portion comprising a sequence complementary to a portion of a disease related gene. Both sets of claims are further drawn to such a primer wherein the disease related gene is APC.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

Art Unit: 1636

problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

May 10, 2006


NANCY VOGEL
PRIMARY EXAMINER